510K Summary

K122855

straumann

DEC 12 2012

1. **Applicant's Name and Address**

Straumann US (on behalf of Institut Straumann AG)
60 Minuteman Rd.
Andover, MA 01810
Telephone Number: 800-448-8168, ext 2513
Fax Number: 978-747-0023
Contact Person: Elaine Alan
Regulatory Project Manager

2. **Date of Submission**: Sept. 17, 2012

3. **Name of the Device**

Trade Name:	Straumann Tissue Level Ø4.1 mm and Ø4.8 mm Roxolid Dental Implants
Common Name:	TL Ø4.1 mm and Ø4.8 mm RXD Dental Implants
Classification Name:	Implant, Endosseous, Root-form
Regulation Number:	§872.3640

4. **Legally Marketed Device to which Equivalence is Claimed (Predicate Device)**

K983742, ITI All-in-One Implant
K003552, ITI Dental Implant System Modification
K033922, ITI Dental Implant System
K003271, ITI Dental Implants
K012757, ITI Tapered Dental Implant
K033984, Dental Implant System Modification, SLActive
K053088, SLActive New Claims
K081419, Modified TE 3.3 RN Implant
K083550, Modified Straumann Dental Implants

5. **Description of the Device**

The proposed Straumann Tissue Level Ø4.1 mm and Ø4.8 mm Roxolid (TiZr) Dental Implants utilize the Straumann Titanium Zirconium material, Roxolid, to the currently cleared Straumann Tissue Level Ø4.1 mm and Ø4.8 mm Titanium dental implants.

The proposed devices are Tissue Level Roxolid dental implants with apical diameters of 4.1 mm and 4.8 mm, and coronal diameters of 4.8 mm and 6.5 mm. The implants will be available in varying lengths of 6.0.to 16mm.

K122855

6. Intended Use of the Device

Straumann® dental implants are suitable for the treatment of oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients (unless specific indications and limitations are present, as stated below). Straumann® dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments). When placing implants in the posterior region, we recommend using only large diameter implants. In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.

7. Technological Characteristics

The body of the proposed implants has a threaded implant body design made of Straumann's Titanium Zirconium (TiZr) Alloy material with Straumann's SLActive surface treatment. The proposed changes are a material change only. There are no changes to the surface treatment, indications for use, fundamental operating principles, or sterilization processes or procedures as a result of the proposed change. No new surgical instruments are being introduced as placement of the proposed implants will follow the established surgical protocols of the currently cleared Straumann Dental Implant Systems. The technological characteristics of the proposed devices are substantially equivalent to the currently marketed devices.

8. Performance Testing

Verification and validation testing were performed to ensure that the devices subject to this 510(k) Premarket Notification function as intended and that design input matches design output. Testing included:

1. Performance Testing

a. Fatigue Testing in accordance to ISO 14801:2007(E), Dentistry-Implants-Dynamic fatigue test for endosseous dental implants.

9. Conclusion

The results from the testing conducted demonstrated that the Straumann Tissue Level Ø4.1 mm and Ø4.8 mm Roxolid Dental Implants function as intended and met the pre-determined acceptance criteria.

The Straumann Dental Implant System is a validated system. The results of the performance bench testing and risk analysis indicate that the Straumann Tissue Level Ø4.1 mm and Ø4.8 Roxolid Dental Implants are substantially equivalent to the named predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 12, 2012

Ms. Elaine Alan
Regulatory Project Manager
Straumann USA
60 Minuteman Road
ANDOVER MA 01810

Re: K122855
Trade/Device Name: Straumann Tissue Level Ø4.1 mm and Ø4.8 mm Roxolid Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: November 12, 2012
Received: November 13, 2012

Dear Ms. Alan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122855

Indications for Use

510(k) Number (if known): K122855

Device Name: Straumann Tissue Level Ø4.1 mm and Ø4.8 mm Roxolid Dental Implants

Indications for Use:

Straumann® dental implants are suitable for the treatment of oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients (unless specific indications and limitations are present, as stated below). Straumann® dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments). When placing implants in the posterior region, we recommend using only large diameter implants. In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.

Prescription Use__X__ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of DCRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2012.12.12 10:43:20 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122855